

REMARKS

Claim Amendments

Claims 1 and 3-5 have been amended herein. Claim 6 has been added herein. Support for the amendments can be found in the claims as originally filed and throughout the specification, for example, at page 3, lines 6 through 10, and Example 1. No new matter has been added.

Drawing Amendments

The drawings are objected to because the figures are not properly labeled. As shown on the attached Replacement Sheet and Annotated Sheet Showing Changes, the drawings are now properly labeled. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 4 and 5 Under 35 U.S.C. §112, First Paragraph

Claims 4 and 5 are rejected under 35 U.S.C. §112, first paragraph.

Claims 4 and 5 have been amended herein to delete the phrase “and/or prevent(ing)” and are now directed to a composition and method of administering said composition to treat malignant tumor and/or metastases thereof. Applicants note that the Examiner has found that “treating” is enabled. Accordingly withdrawal of the rejection is respectfully requested.

Rejection of Claims 1-5 Under 35 U.S.C. §112, Second Paragraph

Claims 1-5 are rejected for various reasons under 35 U.S.C. §112, second paragraph. Applicants will address the rejections in the order the Examiner has made them.

Claims 1-5 are objected to as vague and indefinite because of the use of the term “extract”. Applicants respectfully disagree. Example 1 clearly teaches that whole *Achillea millefolium* was ground and that the extracts were obtained through the use of methanol as the solvent. Additionally, Example 1 teaches how the various extractions were identified based on their retention times. One skilled in the art could easily reproduce the teachings of Example 1 to produce the extractions as claimed. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 4 and 5 are objected to as indefinite because of the use of the term “substantially”. Claims 1, 4 and 5 have been amended herein to delete the recitation of this term. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 3 is objected to as indefinite because the claim does not set forth any steps involved in the method/process. Claim 3 has been amended herein to recite a method setting forth the required step(s). Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claim 3 Under 35 U.S.C. §101

Claim 3 is rejected under 35 U.S.C. §101 as a claim which is not a proper process claim. Claim 3 has been amended herein to recite a method that meets the statutory requirement of 35 U.S.C. §101. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 3 and 5 Under 35 U.S.C. §102(b)

Claims 3 and 5 are rejected under 35 U.S.C. §102(b) as being anticipated by Ishii *et al.* and Tozyo *et al.*

The papers by Ishii *et al.* and Tozyo *et al.* used a leukemia model, for which the biology is distinct from solid tumors. In these studies both leukemia cells and the agents were inoculated via intraperitoneal route. This resembles an *in vitro* petri dish where both cells and agents are mixed together, which does not mimic the more complex human situation where a drug has to cross several barriers and undergo several pharmacological steps before reaching the cancer target. In this context, the model of the present invention is new and more relevant as the solid tumor was implanted sub-cutaneous; metastases progressed from this site through several physiological barriers to invade the lungs. The extract is given by intraperitoneal, which indicate that the active molecules are absorbed and circulate through the blood stream. In summary the model of the present invention, unlike those described by Ishii *et al.* and Tozyo *et al.*, is more relevant and better predict anti-tumor and anti-metastatic activities. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 2, and 4 Under 35 U.S.C. §102(b)

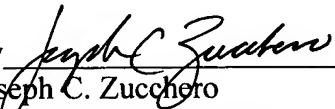
Claims 1, 2, and 4 are rejected under 35 U.S.C. §102(b) as being anticipated by Ishii *et al.* and Tozyo *et al.*

Ishii *et al.* and Tozyo *et al.* do not teach an extract from the *Achillea millefolium* whole dried plant having an anti-tumorogenic and anti-metastatic activity. Rather, Ishii *et al.* and Tozyo *et al.* describe purified compounds from the flowers of *Achillea millefolium* (See Ishii abstract and Tozyo at page 1096, column 1, lines 5-8). Therefore Ishii *et al.* and Tozyo *et al.* do not anticipate the present invention. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

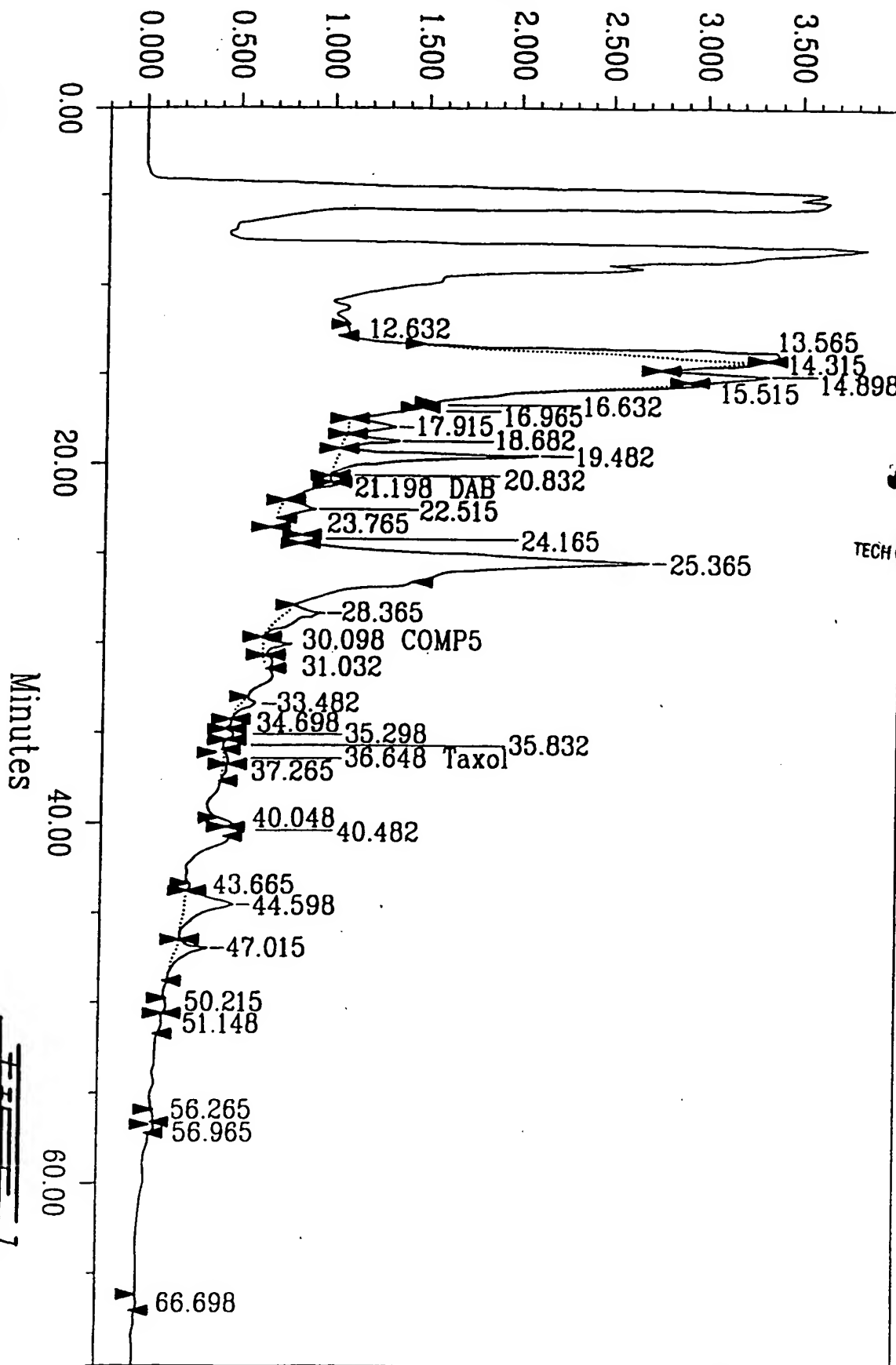
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Dated: June 18 2004

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Annotated Sheet Showing Changes

AU



JUN 25 2004

TECH CENTER 1600/2900

Minutes

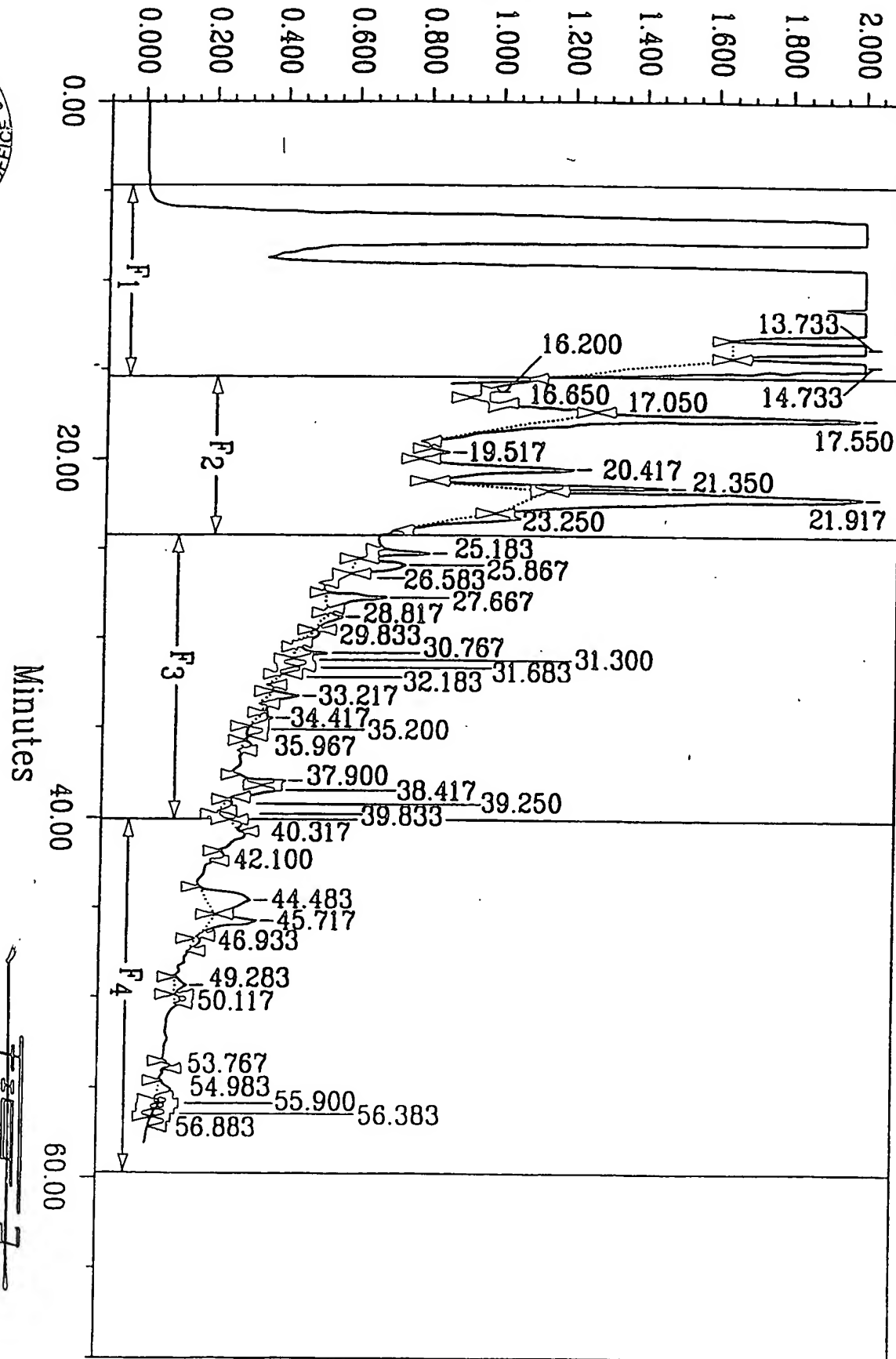


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Figure 1

Annotated Sheet Showing Changes

AU



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TECHNICAL

Minutes



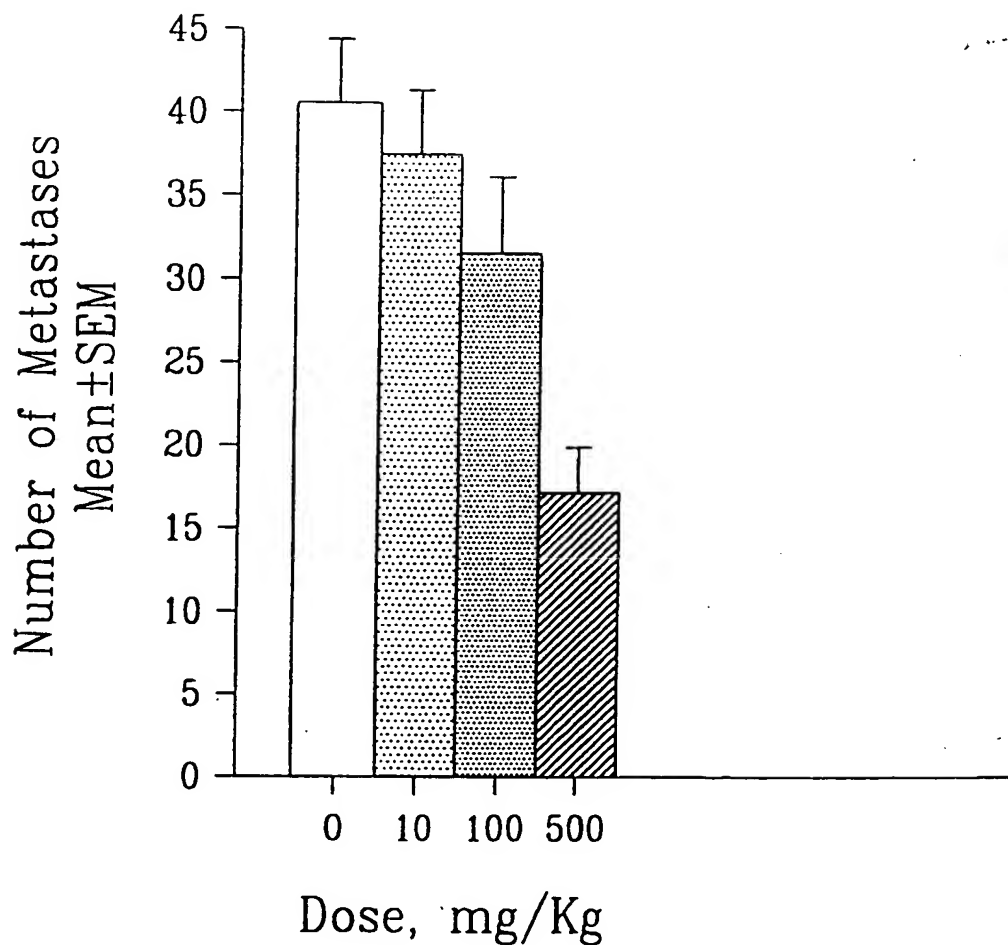
2/4

Figure 2



Annotated Sheet Showing Changes

~~3/4~~



JUN 25 2004

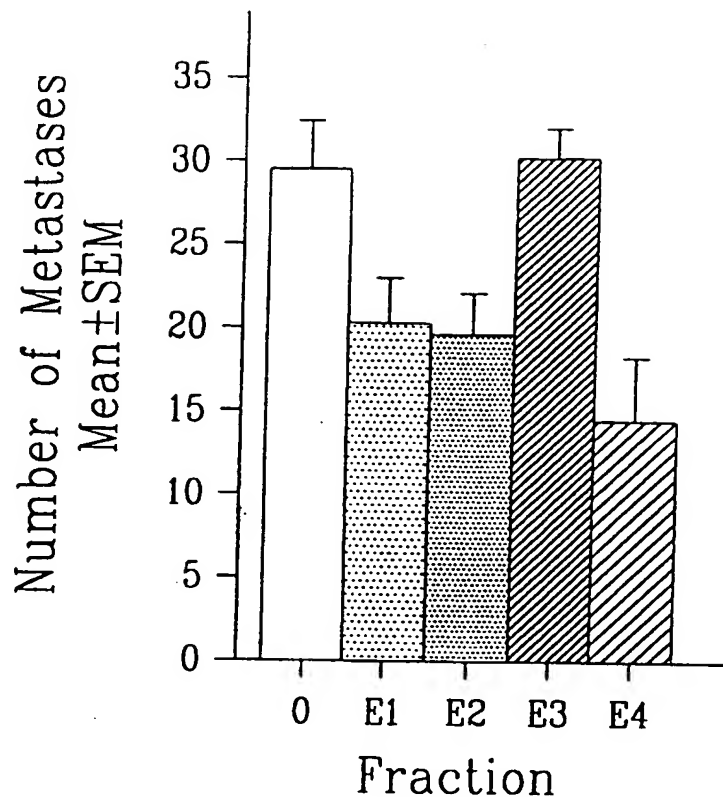
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7 ip administrations every second day
 For each group n=10
 No drug-related death was observed

~~Figure 3~~

Figure 3

Annotated Sheet Showing Changes

~~4/4~~

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E1: 100mg/Kg, 7 ip administrations every second day
 E2: 100mg/Kg, 7 ip administrations every second day
 E3: 100mg/Kg, 7 ip administrations every second day
 E4: 100mg/Kg, 7 ip administrations every second day

ip = intraperitoneal

For each group n=6

No drug-related death was observed

~~Figure 4~~

Figure 4